

UNITED STATES DISTRICT COURT  
SOUTHERN DISTRICT OF NEW YORK

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AMERICAN STOCK TRANSFER & TRUST  
COMPANY, LLC, as trustee,

Plaintiff,

v.

SANOFI,

Defendant.

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Case No. 15 Civ. 8725 (GBD)

ECF CASE

**DECLARATION OF JOSHUA S. AMSEL IN SUPPORT OF  
DEFENDANT’S MOTION TO DISMISS COUNTS II AND III OF THE COMPLAINT**

I, Joshua S. Amsel, under penalty of perjury, declare as follows:

1. I am an attorney admitted to practice before this Court and a partner with the law firm of Weil, Gotshal & Manges LLP, attorneys for Defendant Sanofi in the above-captioned action. I submit this declaration in support of Defendant’s motion to dismiss Counts II and II of the Complaint.

2. True and correct copies of the following exhibits are attached hereto.

<b>Exhibit</b>	<b>Description</b>
1	U.S. Food and Drug Administration (“FDA”), Alemtuzumab Background Package for the Peripheral and Central Nervous System Drugs Advisory Committee Meeting (BLA 103948/5139), dated November 13, 2013 (excerpts) <available at <a href="http://www.fda.gov/downloads/AdvisoryCommittees/CommitteesMeetingMaterials/Drugs/PeripheralandCentralNervousSystemDrugsAdvisoryCommittee/UCM374186.pdf">http://www.fda.gov/downloads/AdvisoryCommittees/CommitteesMeetingMaterials/Drugs/PeripheralandCentralNervousSystemDrugsAdvisoryCommittee/UCM374186.pdf</a> >
2	FDA, Guidance for Industry: E 10 Choice of Control Group and Related Issues in Clinical Trials, dated May 2001 <available at <a href="http://www.fda.gov/downloads/drugs/guidancecomplianceregulatoryinformation/guidances/ucm073139.pdf">http://www.fda.gov/downloads/drugs/guidancecomplianceregulatoryinformation/guidances/ucm073139.pdf</a> >
3	FDA, Center for Drug Evaluation & Research: Manual of Policies & Procedures § 6025.4 <available at <a href="http://www.fda.gov/downloads/aboutfda/centersoffices/officeofmedicalproductsandtobacco/cder/manualofpoliciesprocedures/ucm370948.htm">http://www.fda.gov/downloads/aboutfda/centersoffices/officeofmedicalproductsandtobacco/cder/manualofpoliciesprocedures/ucm370948.htm</a> >

Exhibit	Description
4	Transcript of Peripheral and Central Nervous System Drugs Advisory Committee Meeting, Silver Spring, Maryland (November 13, 2013) <available at <a href="http://www.fda.gov/downloads/AdvisoryCommittees/CommitteesMeetingMaterials/Drugs/PeripheralandCentralNervousSystemDrugsAdvisoryCommittee/UCM386059.pdf">http://www.fda.gov/downloads/AdvisoryCommittees/CommitteesMeetingMaterials/Drugs/PeripheralandCentralNervousSystemDrugsAdvisoryCommittee/UCM386059.pdf</a> >
5	U.S. National Institutes of Health: Comparison of Alemtuzumab and Rebif Efficacy in Multiple Sclerosis, Study One (CARE-MS I) <available at <a href="http://clinicaltrials.gov/ct2/show/NCT00530348">http://clinicaltrials.gov/ct2/show/NCT00530348</a> >
6	U.S. National Institutes of Health: Comparison of Alemtuzumab and Rebif Efficacy in Multiple Sclerosis, Study Two (CARE-MS II) <available at <a href="http://clinicaltrials.gov/ct2/show/NCT00548405">http://clinicaltrials.gov/ct2/show/NCT00548405</a> >
7	Amendment 14 to Genzyme Solicitation/Recommendation Statement on Schedule 14D-9, filed with the U.S. Securities and Exchange Commission (the “SEC”) on December 23, 2010
8	Sanofi Current Report on Form 6-K, filed with the SEC on July 11, 2011 (excerpt)
9	Sanofi Current Report on Form 6-K, filed with the SEC on November 14, 2011 (excerpt)
10	Jeffrey A. Cohen, Alasdair J. Coles, <i>et al.</i> , <i>Alemtuzumab versus interferon beta 1a as first-line treatment for patients with relapsing-remitting multiple sclerosis: a randomized controlled phase 3 trial</i> , 380 Lancet 1819-28 (November 2012)
11	Alasdair J. Coles, Cary L. Twyman, <i>et al.</i> , <i>Alemtuzumab for patients with relapsing multiple sclerosis after disease-modifying therapy: a randomized controlled phase 3 trial</i> , 380 Lancet 1829-39 (November 2012)
12	Sanofi Current Report on Form 6-K, filed with the SEC on July 27, 2012 (excerpt)
13	European Medicines Agency, Summary of Positive Opinion for Lemtrada, June 27, 2013 <available at <a href="http://www.ema.europa.eu/docs/en_GB/document_library/Summary_of_opinion_-_Initial_authorisation/human/003718/WC500144904.pdf">http://www.ema.europa.eu/docs/en_GB/document_library/Summary_of_opinion_-_Initial_authorisation/human/003718/WC500144904.pdf</a> >
14	European Commission, Commission Implementing Decision for Lemtrada, September 12, 2013 <available at <a href="http://ec.europa.eu/health/documents/community-register/2013/20130912126598/dec_126598_en.pdf">http://ec.europa.eu/health/documents/community-register/2013/20130912126598/dec_126598_en.pdf</a> >
15	Health Canada, Drug Product Database: Lemtrada <available at <a href="http://webprod5.hc-sc.gc.ca/dpd-bdpp/info.do?code=90290&amp;lang=eng">http://webprod5.hc-sc.gc.ca/dpd-bdpp/info.do?code=90290&amp;lang=eng</a> >
16	Therapeutic Goods Administration, Product Information for Lemtrada <available at

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	<a href="https://www.ebs.tga.gov.au/ebs/picmi/picmirepository.nsf/pdf?OpenAgent&amp;id=CP-2013-PI-02549-1">https://www.ebs.tga.gov.au/ebs/picmi/picmirepository.nsf/pdf?OpenAgent&amp;id=CP-2013-PI-02549-1</a> >
17	Comisión Federal para la Protección contra Riesgos Sanitarios, Press Release, January 25, 2015: La Secretaría de Salud Autorizó 32 Nuevas Medicinas en 2014 <available at <a href="http://www.cofepris.gob.mx/Documents/NotasPrincipales/25012015.pdf">http://www.cofepris.gob.mx/Documents/NotasPrincipales/25012015.pdf</a> >
18	La Administración Nacional de Medicamentos, Alimentos y Tecnología Médica, Disposición 4377-14: Lemtrada, June 23, 2014 <available at <a href="http://www.anmat.gov.ar/boletin_anmat/Junio_2014/Dispo_4377-14.pdf">http://www.anmat.gov.ar/boletin_anmat/Junio_2014/Dispo_4377-14.pdf</a> >
19	FDA Summary Minutes of the Peripheral and Central Nervous System Drugs Advisory Committee Meeting on November 13, 2013, approved January 14, 2014 <available at <a href="http://www.fda.gov/downloads/AdvisoryCommittees/CommitteesMeetingMaterials/Drugs/PeripheralandCentralNervousSystemDrugsAdvisoryCommittee/UCM386058.pdf">http://www.fda.gov/downloads/AdvisoryCommittees/CommitteesMeetingMaterials/Drugs/PeripheralandCentralNervousSystemDrugsAdvisoryCommittee/UCM386058.pdf</a> >
20	Sanofi Current Report on Form 6-K, filed with the SEC on June 2, 2014 (excerpt)
21	Sanofi Current Report on Form 6-K, filed with the SEC on July 31, 2014 (excerpt)
22	Sanofi Current Report on Form 6-K, filed with the SEC on February 5, 2015 (excerpt)
23	Sanofi Current Report on Form 6-K, filed with the SEC on April 30, 2015 (excerpt)
24	Sanofi Current Report on Form 6-K, filed with the SEC on October 29, 2015 (excerpt)

3. I declare under penalty of perjury that the foregoing is true and correct.

Executed on: January 29, 2016

/s/ Joshua S. Amsel  
Joshua S. Amsel